

**K240596 Cerebral Autoregulation Index (CAI) Algorithm**Oct 16, 2024  
226 days to decisionK240596 · Product code: **MUD** · Neurology  
Source: <https://www.510kdatabase.net/k240596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Mar 4, 2024
Decision date	Oct 16, 2024
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Edwards Lifesciences</b>
Location	Irvine, CA, US
Contact	Daphney Germain-Kolawole
Website	<a href="http://www.edwards.com">http://www.edwards.com</a>
510(k) history	20 submissions · 19 cleared · 2011-2026

Edwards Lifesciences is the leading global structural heart innovation company dedicated to improving patient lives through breakthrough cardiovascular technologies. The company partners with physicians to develop products for patients fighting heart disease, with a manufacturing facility in Irvine, US. Edwards Lifesciences has received FDA 510(k) clearances from total submissions since 2011. The company specializes in Cardiovascular devices, which represent the dominant focus of its regulatory portfolio. The latest clearance in 2025 reflects continued innovation and acti...