

K231038 Global Hypoperfusion Index (GHI) AlgorithmJul 26, 2023
105 days to decisionK231038 · Product code: **QNL** · Cardiovascular
Source: <https://www.510kdatabase.net/k231038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medium-term Adjunctive Predictive Cardiovascular Indicator (QNL)
Date received	Apr 12, 2023
Decision date	Jul 26, 2023
Days to decision	105 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
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...