

K230842 SignalHF (IM008)Oct 25, 2023
211 days to decisionK230842 · Product code: **QNL** · Cardiovascular
Source: <https://www.510kdatabase.net/k230842/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Medium-term Adjunctive Predictive Cardiovascular Indicator (QNL)
Date received	Mar 28, 2023
Decision date	Oct 25, 2023
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Implicity, Inc.
Location	Cambridge, MA, US
Contact	Caroline Florequin
510(k) history	2 submissions · 2 cleared · 2021-2023

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