

K254066 Etiometry PlatformApr 3, 2026
106 days to decisionK254066 · Product code: **PPW** · Cardiovascular
Source: <https://www.510kdatabase.net/k254066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adjunctive Cardiovascular Status Indicator (PPW)
Date received	Dec 18, 2025
Decision date	Apr 3, 2026
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Etiometry, Inc.
Location	Boston, MA, US
Contact	Timothy Hanson
Website	https://www.etiometry.com
510(k) history	11 submissions · 11 cleared · 2015-2026

Etiometry, Inc. is a clinical decision-support software company founded in 2010. Based in Boston, the company develops AI-driven clinical intelligence platforms for intensive care settings. The platform aggregates patient data, provides risk analytics, automates clinical pathways, and supports quality improvement initiatives in high-acuity care environments. Etiometry has received FDA 510(k) clearances from total submissions since 2015. The company specializes exclusively in Cardiovascular devices and software solutions. The latest clearance in 2026 demonstrates continued...

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Device record: <https://www.510kdatabase.net/k254066/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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