

K213230 T3 Platform SoftwareJun 22, 2022
266 days to decisionK213230 · Product code: **PPW** · Cardiovascular
Source: <https://www.510kdatabase.net/k213230/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Cardiovascular Status Indicator (PPW)
Date received	Sep 29, 2021
Decision date	Jun 22, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Etiometry, Inc.
Location	Boston, MA, US
Contact	Tim 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/k213230/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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