

**K213423 T3 Platform software**Jan 6, 2023  
443 days to decisionK213423 · Product code: **PLB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k213423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multivariate Vital Signs Index (PLB)
Date received	Oct 20, 2021
Decision date	Jan 6, 2023
Days to decision	443 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Etiometry, Inc.</b>
Location	Boston, MA, US
Contact	Tim Hanson
Website	<a href="https://www.etiometry.com">https://www.etiometry.com</a>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k213423/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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