

**K152258 T3 Software**Mar 31, 2016  
233 days to decisionK152258 · Product code: **PLB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152258/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multivariate Vital Signs Index (PLB)
Date received	Aug 11, 2015
Decision date	Mar 31, 2016
Days to decision	233 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Etiometry, Inc.</b>
Location	Boston, MA, US
Contact	DIMITAR BARONOV
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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