

**K250649 Bunkerhill ECG-EF**Sep 19, 2025  
199 days to decisionK250649 · Product code: **QYE** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250649/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reduced Ejection Fraction Machine Learning-based Notification Software (QYE)
Date received	Mar 4, 2025
Decision date	Sep 19, 2025
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BunkerHill Health</b>
Location	San Francisco, CA, US
Contact	Nishith Khandwala
510(k) history	8 submissions · 8 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells LLP</b>
Contact	John Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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