

K243779 Bunkerhill Abdominal Aortic Quantification (AAQ)Jul 1, 2025
204 days to decisionK243779 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243779/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 9, 2024
Decision date	Jul 1, 2025
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243779/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026