

K250662 Bunkerhill MACOct 3, 2025
212 days to decisionK250662 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k250662/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 5, 2025
Decision date	Oct 3, 2025
Days to decision	212 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 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/k250662/> 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 14, 2026