

K250337 AiORTA - PlanOct 30, 2025
266 days to decisionK250337 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 6, 2025
Decision date	Oct 30, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ViTAA Medical Solutions, Inc.
Location	Montreal, CA
Contact	Mitchel Benovoy
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Bml Health, Inc.
Contact	Marc Saab

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/k250337/> 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