

K243065 Cardiac GuidanceJan 15, 2025
110 days to decisionK243065 · Product code: **QJU** · Radiology
Source: <https://www.510kdatabase.net/k243065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Acquisition And/or Optimization Guided By Artificial Intelligence (QJU)
Date received	Sep 27, 2024
Decision date	Jan 15, 2025
Days to decision	110 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Caption Health, Inc.
Location	Brisbane, CA, US
Contact	Tahir Rizvi
510(k) history	2 submissions · 1 cleared · 2023-2025

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