FDA 510(k) Premarket Notification

K250670 EchoConfidence (USA)

CLEARED

Jun 30, 2025
117 days to decision

K250670 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k250670/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 5, 2025
Decision date	Jun 30, 2025
Days to decision	117 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mycardium AI Limited**
Location	Liverpool, GB
Contact	Michael Walker
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	**Hardian Health Ltd T/A Hardian Health**
Contact	Michael Pogose

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