FDA 510(k) Premarket Notification

K242062 1CMR Pro

CLEARED

Nov 15, 2024
123 days to decision

K242062 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k242062/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 15, 2024
Decision date	Nov 15, 2024
Days to decision	123 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 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