

K221640 AlloMap Heart Molecular Expression TestingSep 13, 2023
464 days to decisionK221640 · Product code: **OJQ** · Chemistry
Source: <https://www.510kdatabase.net/k221640/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cardiac Allograft Gene Expression Profiling Test System (OJQ)
Date received	Jun 6, 2022
Decision date	Sep 13, 2023
Days to decision	464 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CareDx, Inc.
Location	Brisbane, CA, US
Contact	Camilla Lu
510(k) history	1 submissions · 1 cleared · 2023-2023

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