

K240860 EchoGo Amyloidosis (1.0)Nov 15, 2024
232 days to decisionK240860 · Product code: **SDJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k240860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Cardiac Amyloidosis Status Indicator (SDJ)
Date received	Mar 28, 2024
Decision date	Nov 15, 2024
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ultromics Limited
Location	Oxford, GB
Contact	Jaco Jacobs
510(k) history	4 submissions · 4 cleared · 2021-2024

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