

K240013 EchoGo Heart Failure (2.0)Sep 23, 2024
265 days to decisionK240013 · Product code: **QUO** · CardiovascularSource: <https://www.510kdatabase.net/k240013/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Heart Failure Status Indicator (QUO)
Date received	Jan 2, 2024
Decision date	Sep 23, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240013/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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