FDA 510(k) Premarket Notification

K240013 EchoGo Heart Failure (2.0)

CLEARED

Sep 23, 2024
265 days to decision

K240013 · Product code: **QUO** · Cardiovascular
Source: 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