FDA 510(k) Premarket Notification

K222463 EchoGo Heart Failure

CLEARED

Nov 23, 2022
100 days to decision

K222463 · Product code: **QUO** · Cardiovascular
Source: https://www.510kdatabase.net/k222463/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adjunctive Heart Failure Status Indicator (QUO)
Date received	Aug 15, 2022
Decision date	Nov 23, 2022
Days to decision	100 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